We claim:

1. An aerosol composition of an aqueous dispersion of nanoparticulate drug particles, wherein:

(a) essentially each droplet of the aerosol comprises at least one nanoparticulate drug particle;

(b) the droplets are of a respirable size; and

(c) the nanoparticulate drug particles comprise a poorly soluble crystalline drug, have an effective average particle size of less than about 1000 nm, and have a surface modifier adsorbed on the surface thereof.

2. The aerosol composition of claim 1, wherein the drug is selected from the group consisting of proteins, peptide, bronchodilators, corticosteroids, elastase inhibitors, analgesics, anti-fungals, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, an analgesic, and a cardiovascular agent.

3. The aerosol composition of claim 1, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

4. The aerosol composition of claim 1, wherein the aerosol comprises a concentration of a drug in an amount of from about 0.05 mg/mL up to about 600 mg/mL.

5. The aerosol composition of claim 4, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/mL or more,

about 100 mg/mL or more, about 200 mg/mL or more, about 400 mg/mL or more, and about 600 mg/mL.

6. The aerosol composition of claim 1, wherein the droplets of the aerosol have a MMAD of about 2 to about 10 microns.

7. The aerosol composition of claim 6, wherein the droplets of the aerosol have a MMAD of from about 2 to about 6 microns.

8. The aerosol composition of claim 1, wherein the droplets of the aerosol have a MMAD of less than about 2 microns.

9. The aerosol composition of claim 1, wherein the droplets of the aerosol have an MMAD of about 5 to about 100 microns .

10. The aerosol composition of claim 9, wherein the droplets of the aerosol have an MMAD of about 30 to about 60 microns.

11. A spray-dried powder aerosol composition comprising aggregates of nanoparticulate drug particles, wherein:

(a) the nanoparticulate drug particles comprise a poorly soluble crystalline drug, have an effective average particle size of less than about 1000 nm, and have a surface modifier adsorbed on the surface thereof; and

(b) the aggregates of spray-dried drug particles have a respirable size.

12. The aerosol composition of claim 11 further comprising a diluent.

13. The aerosol composition of claim 12, wherein essentially every diluent particle comprises at least one embedded nanoparticulate drug particle having a surface modifier adhered to the surface of the drug particle.

14. The aerosol composition of claim 11, wherein the drug is selected from the group consisting of proteins, peptides, bronchodilators, corticosteroids, elastase inhibitors, analgesics, anti-fungals, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, an analgesic, and a cardiovascular agent.

15. The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

16. The aerosol composition of claim 11, wherein the aerosol comprises a concentration of a drug in an amount of from about 0.05 mg/g up to about 900 mg/g.

17. The aerosol composition of claim 16, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/g or more, about 100 mg/g or more, about 200 mg/g or more, about 400 mg/g or more, about 600 mg/g or more, and about 900 mg/g.

18. The aerosol composition of claim 11, wherein the aggregates of the nanoparticulate drug particles have a MMAD of about 2 to about 10 microns.

19. The aerosol composition of claim 18, wherein the aggregates of the nanoparticulate drug particles have a MMAD of about 2 to about 6 microns.

20. The aerosol composition of claim 11, wherein the aggregates of the nanoparticulate drug particles have a MMAD of less than about 2 microns.

21. The aerosol composition of claim 11, wherein the aggregates of the nanoparticulate drug particles have a MMAD of about 5 to about 100 μm.

22. The aerosol composition of claim 21, wherein the aggregates of the nanoparticulate drug particles have a MMAD of about 30 to about 60 μm.

23. A freeze-dried powder aerosol composition comprising aggregates of nanoparticulate drug particles, wherein:

(a) the aggregates of freeze-dried drug particles have a respirable particle size; and

(b) the nanoparticulate drug particles comprise a poorly soluble crystalline drug, have an effective average particle size of less than about 1000 nm, and have a surface modifier adsorbed on the surface thereof.

24. The aerosol composition of claim 23, further comprising a diluent.

25. The aerosol composition of claim 23, wherein the drug is selected from the group consisting of proteins, peptides, bronchodilators, corticosteroids, elastase inhibitors, analgesics, anti-fungals, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, an analgesic, and a cardiovascular agent.

26. The aerosol composition of claim 23, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less

than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

27. The aerosol composition of claim 23, wherein the aerosol comprises a concentration of a drug in an amount of from about 0.05 mg/g up to about 900 mg/g.

28. The aerosol composition of claim 27, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/g or more, about 100 mg/g or more, about 200 mg/g or more, about 400 mg/g or more, about 600 mg/g or more, and about 900 mg/g.

29. The aerosol composition of claim 23, wherein the aggregates of the nanoparticulate drug particles have a MMAD of about 2 to about 10 microns.

30. The aerosol composition of claim 29, wherein the aggregates of the nanoparticulate drug particles have a MMAD of about 2 to about 6 microns.

31. The aerosol composition of claim 23, wherein the aggregates of the nanoparticulate drug particles have a MMAD of less than about 2 microns.

32. The aerosol composition of claim 23, wherein the aggregates of the nanoparticulate drug particles have a MMAD of about 5 to about 100 μm.

33. The aerosol composition of claim 32, wherein the aggregates of the nanoparticulate drug particles have a MMAD of about 30 to about 60 μm.

34. The aerosol composition of claim 23, further comprising spray-dried nanoparticulate drug powder, wherein the drug of the freeze-dried nanoparticulate drug powder is either the same or different from the drug of the spray-dried nanoparticulate drug powder.

35. A dry powder nanoparticulate aerosol composition for use in a propellant-based pMDI comprising

(a) aggregates of a nanoparticulate poorly soluble crystalline drug, wherein the drug has a surface modifier adsorbed on the surface thereof, and the drug has an effective average particle size of less than about 1000 nm, wherein the aggregates have a respirable size, and

(b) a non-aqueous propellant.

36. The aerosol composition of claim 35, wherein the propellant is a non-CFC propellant.

37. A nanoparticulate aerosol composition for use in a propellant-based pMDI comprising

(a) a nanoparticulate poorly soluble crystalline drug, wherein the drug has a surface modifier adsorbed on the surface thereof, and the drug has an effective average particle size of less than about 1000 nm, and

(b) a non-aqueous propellant.

38. The aerosol composition of claim 37, wherein the propellant is a non-CFC propellant.

39. A method of making an aerosol of an aqueous dispersion of nanoparticulate drug particles, wherein said nanoparticulate drug particles comprise a poorly soluble crystalline drug, have an effective average particle size of less than about 1000 nm, and have a surface modifier adsorbed on the surface thereof; wherein the method comprises:

(a) providing an aqueous dispersion of said nanoparticulate drug particles; and

(b) nebulizing said dispersion to form an aerosol, wherein essentially each droplet of the aerosol comprises at least one nanoparticulate drug particle and a surface modifier, and wherein the droplets are of a respirable size.

40. A method of making a dry powder nanoparticulate drug composition comprising:

(a) forming an aqueous nanoparticulate dispersion of a poorly soluble drug, wherein the dispersion comprises crystalline drug particles and a surface modifier adsorbed on the surface thereof, wherein the drug particles have an effective average particle size of less than about 1000 nm;

(b) spray-drying the nanoparticulate dispersion to form a dry powder of aggregates of the nanoparticulate drug and surface modifier particles, wherein the aggregates are of a respirable size.

41. The method of claim 40, further comprising adding a diluent to the nanoparticulate dispersion prior to spray-drying, wherein following spray-drying essentially every diluent particle contains at least one embedded drug particle and a surface modifier.

42. A method of making a dry powder nanoparticulate drug aerosol formulation comprising:

(a) milling under non-pressurized conditions a poorly soluble crystalline drug and a surface modifier in a non-aqueous medium having a high boiling point to obtain a nanoparticulate drug composition having an effective average particle size of less than about 1000 nm, and

(b) evaporating the non-aqueous medium to obtain a dry powder of aggregates of drug and surface modifier particles, wherein the aggregates are of a respirable size.

43. A method of making a nanoparticulate drug aerosol formulation comprising:

(a) milling under pressurized conditions a poorly soluble crystalline drug and a surface modifier in a non-aqueous medium; and

(b) evaporating the non-aqueous medium to obtain a dry powder of aggregates of drug and surface modifier particles, wherein the aggregates are of a respirable size.

44. A method of making a dry powder nanoparticulate drug composition comprising:

(a) forming an aqueous nanoparticulate dispersion of a poorly soluble drug, wherein the dispersion comprises crystalline drug particles and a surface modifier adsorbed on the surface thereof, wherein the drug particles have an effective average particle size of less than about 1000 nm;

(b) freeze-drying the nanoparticulate dispersion to form a dry powder of aggregates of the nanoparticulate drug and surface modifier particles, wherein the aggregates are of a respirable size.

45. The method of claim 44, further comprising adding a diluent to the nanoparticulate dispersion prior to freeze-drying, wherein following freeze-drying essentially every diluent particle contains at least one embedded drug particle and a surface modifier.

46. A method of administering the aerosol of claim 1 to a patient, wherein the aerosol comprises drug at a concentration of 10 mg/mL or greater, and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.

47. A method of administering the aerosol of claim 11 to a patient, wherein the aerosol comprises drug at a concentration of 10 mg/g or greater, and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.

48. A method of administering the aerosol of claim 23 to a patient, wherein the aerosol comprises drug at a concentration of 10 mg/g or greater, and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.

49. A method of administering the aerosol of claim 35 to a patient, wherein the aerosol comprises drug at a concentration of 10 mg/g or greater, and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.

50. A method of administering the aerosol of claim 37 to a patient, wherein the aerosol comprises drug at a concentration of 10 mg/g or greater, and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.

add A2
add B1

Add C3